

service area is de-certified and all administrative appeals under § 486.314 are exhausted.

(b) Designation periods—

(1) *General.* An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) *Re-Certification.* Re-certification must occur not more frequently than once every 4 years.

(c) Unless CMS has granted a hospital a waiver under paragraphs

(d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

(d) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, CMS considers—

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the definitions

of metropolitan statistical areas, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§ 486.309 Re-certification from August 1, 2006 through July 31, 2010.

An OPO will be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Agreements based on the August 1, 2006 through July 31, 2010 re-certification cycle will end on January 31, 2011.

§ 486.310 Changes in control or ownership or service area.

(a) *OPO requirements.*

(1) A designated OPO considering a change in control (see § 413.17(b)(3)) or ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership.

(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of control or ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

(b) *CMS requirements.*